DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

October 6, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2938475

Jon Katis, Owner
Empire Home Medical, Inc.
12520 Loma Rica Drive
Grass Valley, CA 95945

Dear Mr. Katis:

During a September 22-23, 1998 inspection of your firm located at 12521 Loma Rica Drive, Grass Valley, CA 95945, FDA Investigator Carl A. Anderson documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's repacking of Oxygen, USP. These deviations cause the drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. You have failed to adequately test Oxygen, USP for identity and strength. Your firm may comply with this regulation by obtaining an acceptable certificate of analysis (COA) from your supplier. Currently the documentation that you receive from your supplier does not include a valid COA [21 CFR 211.165(a)].

2. You have failed to properly calibrate your [redacted] Oxygen Analyzer (i.e., not using a certified calibration gas). The COA for your calibration gas is not valid in that it lacks the test method used in analysis [21 CFR 211.160(b)(4)].

3. You have failed to establish a training program in current Good Manufacturing Practices (CGMPs) on a continuing basis and with sufficient frequency to assure that employees are familiar with the CGMP requirements applicable to them. [21 CFR 211.25(a)].

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the Act and that regulations are being met.

Enclosed are a copy of the Food and Drug Administration's Booklet entitled Compressed Medical Gases Outline and 21 CFR Part 211. You have at your firm a copy of "Fresh Air '98" by Mr. Duane Sylvia of FDA's Office of Compliance, Division of Manufacturing and Product Quality, Center for Drug Evaluation and Research. Mr. Sylvia's speech and Compressed Medical Gases Outline contain useful information on how to comply with the requirements of 21 CFR Part 211.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 304) and for Injunction (Section 302) of the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time needed to complete the corrections.

Please submit your response to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, 94502-7070, attention: Frank W. Scholl, Supervisory Consumer Safety Officer.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director

Enclosures:

Compressed Medical Gases Guideline
21 CFR Part 211